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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/074,272 | 02/14/2002 | Robert K. Yang | 1199-4 | 4926 |

7590 10/03/2005

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EXAMINER

CHAN, SING P

ART UNIT PAPER NUMBER

1734

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/074,272

Applicant(s)

YANG ET AL.

Examiner

Sing P. Chan

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54,55,62-78,80,81 and 83-119 is/are pending in the application.
- 4a) Of the above claim(s) 54,55,62-78,80,81 and 83-90 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 91-119 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/26/04 & 7/11/05</u> 4/12/04 | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Claims 54, 55, 62-78, 80, 81, 83-90 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 11, 2005 to reflect a shift of invention.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: The reference character "40" labeling an application roller is not mentioned. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claim 119 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/768,809. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both recite combining a polymer component and polar solvent, to form a matrix with a uniform distribution, forming a film from said matrix, providing a surface having top and bottom side, feeding said film onto said top side of said surface, and drying said film by applying heat to bottom side of said surface. Although, claim 119 of instant application does not recite the matrix include an active component, exposing the film to a temperature above a degradation temperature of the active component wherein the active component is maintained at a desired level, the claim does not exclude such limitation.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 119 is rejected under 35 U.S.C. 102(b) as being anticipated by Magoon (U.S. 4,631,837).

Magoon discloses a method of forming fruit leather. The method includes providing a fruit pulp puree, (Col 2, lines 37-38) which inherently includes water soluble polymer component such as dietary fiber or polysaccharides and a polar solvent such as fruit juice/water, applying the puree onto a polyester sheet on hot water, which heat the puree from the bottom up and dries the puree (Col 2, lines 25-40).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 91-93, 97, 100, 101, 104-109, 111-115, 117-119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zerbe et al (U.S. 6,660,292) in view of Strobush et al (U.S. 5,881,476).

Regarding claims 91-93, 97, 100, 101, 104-109, 111-118, and 119, Zerbe et al ('292) discloses a method of forming flavored film. The method includes providing a polymer component such as hydroxypropyl cellulose, modified starch, flavoring and other ingredients in water to form a solution, i.e. a matrix, coating the matrix onto a carrier substrate such as kraft paper or siliconized polyethylene-terephthalate film (Col 5, lines 36-45) and drying the film with hot air and removing the film after drying (Col 6, lines 43-50). Zerbe et al ('292) is silent as to the hot air is applied to the bottom of the substrate with air current's velocity at the bottom is higher than the top or substantially no top air flow to dry the film. However, directing hot air to the bottom of the substrate with a higher air current at the bottom than the top or substantially no top air flow to dry the film is well known and conventional as shown for example by Strobush et al. Strobush et al discloses a method for drying a coating on a substrate. The method includes providing a substrate with a coating applied to a substrate (Col 8, line 66 to Col 9, line 8), providing a drying apparatus, feeding the coated substrate into the apparatus, where air foils (30) located below the coated substrate direct drying gas, i.e. heated air or hot air, to the bottom surface of the coated substrate (Col 9, lines 44-51) with air bars (34) to supply top-side gas or fresh air for added drying or to carry away evaporated solvent or no gas is supplied when top-side gas is not needed or desired (Col 11, lines 15-27) to dry the film without mottle defects, i.e. uniform thickness. (Col 12, lines 27-31)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to dry the coating on a substrate by directing drying gas to the bottom of the coated substrate as disclosed by Strobush et al in the method of Zerbe et al ('292) to dry the coating on a substrate without mottle and at a higher web speeds. (See Strobush et al, Col 6, lines 21-27)

9. Claims 94 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zerbe et al (U.S. 6,660,292) in view of Strobush et al (U.S. 5,881,476) as applied to claim 91 above, and further in view of Horstmann et al (U.S. 5,629,003).

Zerbe et al ('292) as modified above is silent as to the thickness of the film is at least 30 μm or at least 500 μm . However, forming an edible film with a thickness of at least 30 μm or at least 500 μm is well known and conventional as shown for example by Horstmann et al. Horstmann et al discloses a method of forming an edible film. The method includes providing a polymer matrix with starch and water (Col 3, lines 49-67 and forming the coating layer to a thickness of 0.003 to 4 mm (Col 4, lines 17-26.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an edible film with a thickness of 0.003 to 4 mm as disclosed by Horstmann et al in the method of Zerbe et al as modified by Strobush et al to provide an edible film having the desired physical characteristics, e.g. strength and texture.

10. Claim 96 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zerbe et al (U.S. 6,660,292) in view of Strobush et al (U.S. 5,881,476) as applied to claim 91 above, and further in view of Wittwer (U.S. 4,478,658).

Zerbe et al ('292) as modified above is silent as to the polymer matrix viscosity is about 400 to 100,000 cps. However, forming edible film using polymer matrix with a viscosity between 400 to 100,000 cps is well known and conventional as shown for example by Wittwer. Wittwer discloses a method of forming an edible film for label. The film is formed of material such as cellulose, starches, and carbohydrates (Col 4, lines 54-69) in a solution with water (Col 5, lines 10-24) and has a viscosity of 2,000 to 2,500 cps (Col 10, lines 37-48).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the matrix with a viscosity of 2,000 to 2,500 cps as disclosed by Wittwer in the method of Zerbe et al '292 as modified by Strobush et al to provide a material suitable for high speed commercial application. (See Wittwer, Col 3, lines 57-59)

11. Claims 98, 99, 102, and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zerbe et al (U.S. 6,660,292) in view of Strobush et al (U.S. 5,881,476) as applied to claim 97 and 101 above, and further in view of Zerbe et al (U.S. 6,231,957).

Zerbe et al ('292) as modified above is silent as to dividing the film into dosage form with equal dimensions, which has the same mass and thickness and packaging each individual dosage forms. However, dividing the film into dosage form with equal dimensions, which has the same mass and thickness and packaging the each individual dosage forms is well known and conventional as shown for example by Zerbe et al ('957). Zerbe et al ('957) discloses a method of forming an edible film. The method

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includes manufacturing the edible film using conventional coating and drying techniques, cut the film into pieces of a shape and size that meet the requirements of intended application, and packing the films or dosage into containers. (Col 3, line 65 to Col 4, line 16)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to cut the film into pieces of a shape and size that meet the requirement of intended application and packing the films or dosage into containers as disclosed by Zerbe et al ('957) in the method of Zerbe et al ('292) as modified by Strobush et al to provide an easy-to-use, cheap, and reproducible flavoring or intermediates. (See Zerbe et al ('957), Col 1, lines 18-21)

12. Claim 110 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zerbe et al (U.S. 6,660,292) in view of Strobush et al (U.S. 5,881,476) and Horstmann et al (U.S. 5,629,003).

Zerbe et al ('292) discloses a method of forming flavored film. The method includes providing a polymer component such as hydroxypropyl cellulose, modified starch, flavoring and other ingredients in water to form a solution, i.e. a matrix, coating the matrix onto a carrier substrate such as kraft paper or siliconized polyethylene-terephthalate film (Col 5, lines 36-45) and drying the film with hot air and removing the film after drying (Col 6, lines 43-50). Zerbe et al ('292) is silent as to the hot air is applied to the film and the thickness of at least 500 μm . However, directing hot air to the bottom of the coated substrate with a hot air current to dry the film is well known and conventional as shown for example by Strobush et al. Strobush et al discloses a

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method for drying a coating on a substrate. The method includes providing a substrate with a coating applied to a substrate (Col 8, line 66 to Col 9, line 8), providing a drying apparatus, feeding the coated substrate into the apparatus, where air foils (30) located below the coated substrate direct drying gas, i.e. heated air or hot air, to the bottom surface of the coated substrate (Col 9, lines 44-51) with air bars (34) to supply top-side gas or fresh air for added drying or to carry away evaporated solvent or no gas is supplied when top-side gas is not needed or desired (Col 11, lines 15-27) to dry the film without mottle defects, i.e. uniform thickness. (Col 12, lines 27-31)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to dry the coating on a substrate by directing drying gas to the bottom of the coated substrate as disclosed by Strobush et al in the method of Zerbe et al ('292) to dry the coating on a substrate without mottle and at a higher web speeds. (See Strobush et al, Col 6, lines 21-27) Zerbe et al ('292) as modified above is silent as to the thickness of the film is at least 500 μm . However, forming an edible film with a thickness of at least 500 μm is well known and conventional as shown for example by Horstmann et al. Horstmann et al discloses a method of forming an edible film. The method includes providing a polymer matrix with starch and water (Col 3, lines 49-67 and forming the coating layer to a thickness of 0.003 to 4 mm (Col 4, lines 17-26.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an edible film with a thickness of 0.003 to 4 mm as disclosed by Horstmann et al in the method of Zerbe et al as modified by Strobush et al

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to provide an edible film having the desired physical characteristics, e.g. strength and texture.

13. Claim 116 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zerbe et al (U.S. 6,660,292) in view of Strobush et al (U.S. 5,881,476) and Mehra et al (U.S. 5,733,575).

Zerbe et al ('292) discloses a method of forming flavored film. The method includes providing a polymer component such as hydroxypropyl cellulose, modified starch, flavoring and other ingredients in water to form a solution, i.e. a matrix, coating the matrix onto a carrier substrate such as kraft paper or siliconized polyethylene-terephthalate film (Col 5, lines 36-45) and drying the film with hot air and removing the film after drying (Col 6, lines 43-50). Zerbe et al ('292) is silent as to the hot air is applied to the bottom of the substrate to dry the film and the matrix includes anti-foaming agent. However, directing hot air to the bottom of the substrate with a higher air current at the bottom than the top or substantially no top air flow to dry the film is well known and conventional as shown for example by Strobush et al. Strobush et al discloses a method for drying a coating on a substrate. The method includes providing a substrate with a coating applied to a substrate (Col 8, line 66 to Col 9, line 8), providing a drying apparatus, feeding the coated substrate into the apparatus, where air foils (30) located below the coated substrate direct drying gas, i.e. heated air or hot air, to the bottom surface of the coated substrate (Col 9, lines 44-51) with air bars (34) to supply top-side gas or fresh air for added drying or to carry away evaporated solvent or

no gas is supplied when top-side gas is not needed or desired (Col 11, lines 15-27) to dry the film without mottle defects, i.e. uniform thickness. (Col 12, lines 27-31)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to dry the coating on a substrate by directing drying gas to the bottom of the coated substrate as disclosed by Strobush et al in the method of Zerbe et al ('292) to dry the coating on a substrate without mottle and at a higher web speeds. (See Strobush et al, Col 6, lines 21-27) Zerbe et al as modified above is silent as to the matrix includes anti-foaming agent. However, providing an anti-foaming agent in the matrix of an edible film is well known and conventional as shown for example by Mehra et al. Mehra et al discloses a method of forming an edible film. The method includes providing a composition with enteric film forming polymer, detackifier, viscosity modifier and an antifoaming agent (Col 2, lines 45-50), which the anti-foaming agent would inherently release oxygen from the composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide anti-foaming agent to the matrix as disclosed by Mehra in the method of Zerbe et al as modified by Strobush et al to provide a less tacky coating or film. (See Mehra, Col 1, lines 65-67)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sing P. Chan whose telephone number is 571-272-1225. The examiner can normally be reached on Monday-Thursday 7:30AM-11:00AM and 12:00PM-4:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher A. Fiorilla can be reached on 571-272-1187. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chan Sung B

SPC

CA Fiorilla

CHRIS FIORILLA
SUPERVISORY PATENT EXAMINER

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